

REMARKS

In the Office Action, the Examiner rejected claims 1-3, 5, 6, and 8 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,310,036 to Browdie in view of U.S. Patent No. 5,209,776 to Bass et al.; and rejected claims 4 and 7 under 35 U.S.C. § 103 as being unpatentable over Browdie in view of Bass et al. and further in view of U.S. Patent no. 5,713,891 to Poppas.

Applicants have amended claim 1 and added new claim 9. Claim 1-9 are pending in the above-captioned patent application.

Applicants respectfully traverse the Examiner's rejection of claims 1-3, 5, 6, and 8 under 35 U.S.C. § 103(a) as being unpatentable over Browdie in view of Bass et al. Claim 1, for example, is not obvious over Browdie and Bass et al. because neither reference taken alone or in combination teaches or suggests each and every element of the claim. In particular, both Browdie and Bass et al. at least fail to teach the claimed method including providing an adhesive, "said adhesive including collagen, a concentration of said collagen in said adhesive being at least equal to 300 mg/ml, but less than 800 mg/ml, said collagen being gelatinized by application of thermal energy, and said collagen being derivatized with a COO⁻ functional group," as recited in claim 1.

The Examiner contends that "Browdie discloses the claimed concentration of collagen: Column 6, lines 15-18 the solution is said to have 35% to 45% concentration of collagen." Office Action at page 2. The Examiner further asserts that "[t]hese percentages translate into 350 mg/mL to 450 mg/m because a concentration is, by definition, in units of mass per unit volume." Id. Applicants respectfully disagree and note that mere disclosure of a concentration in terms of percentages alone does not

necessarily connote a concentration in units of mass per unit volume. For example, the percentage may be a volume/volume percentage or a weight/weight percentage of solvent to solute.

In any event, the Examiner further argues that "Applicant defines 'gelatinization' very broadly from pages 6-7 of the specification as forming something into a viscous liquid, gel, or solid." To the extent the Examiner's assertion concerning the specification's "very" broad definition of gelatinization is understood, Applicants respectfully note that pages 6 and 7 of the specification describe an "Exemplary Preparation of Pure Type I Collagen Solutions" (specification at page 6, line 7). Applicants respectfully submit that the Examiner's citation to pages 6-7 of the specification is misplaced, and direct the Examiner's attention to exemplary description of gelatinization of collagen consistent with an aspect of Applicant's disclosure in other portions of Applicants' specification. In particular, Applicants note page 10, line 20 of the specification, which describes "thermal energy causing the gelatinization of collagen."

The Examiner's assertions notwithstanding, the specification does *not* define gelatinized collagen as merely being in a liquid, gel or solid form. Instead, the specification describes gelatinization of collagen through application of thermal energy, such as microwave energy, to the collagen. *Id.* As pointed out in Applicants' Amendment After Final dated March 23, 2004, such heating, for example, is believed to cause derivatized collagen to be broken down into smaller molecular weight units (Amendment After Final at page 6).

Accordingly, gelatinized collagen is collagen that has been heated sufficiently. To highlight this point, Applicants have amended claim 1 to recite that the claimed collagen is "gelatinized by application of thermal energy." Browdie does not disclose application of thermal energy nor heating of collagen. To the contrary, as acknowledged by the Examiner, Browdie describes *cold* lyophilization (col. 6, lines 15-17), and in this respect teaches away from the claimed gelatinized collagen "by application of thermal energy." Thus, Browdie necessarily fails to teach the claimed method including providing an adhesive having such gelatinized collagen "by application of thermal energy," as recited in claim 1.

Applicant notes that the Examiner apparently concedes that Browdie is silent as to express or "verbatim" disclosure of the claimed derivatized collagen (Office Action at page 3). Nevertheless, the Examiner further contends that "*Browdie discloses the same process as the Applicant's for treating his collagen*" (emphasis in original), and therefore, according to the Examiner, the reference has "the same outcome as the Applicant." To the extent, the Examiner's position is understood, Applicants respectfully point out that their disclosed exemplary derivatization of collagen, as set forth in the specification, is *not* the same as that set forth in Browdie. Since Browdie otherwise fails to teach collagen that is both gelatinized and derivatized with a COO⁻ functional group, Applicant submits that Browdie does not teach or suggest Applicants' claimed method including providing an adhesive having such collagen.

As noted in Applicants' Amendment After Final, the term "derivatized" is a commonly used term in protein chemistry to denote modification of a protein molecule whereby a functional group present on a protein molecule reacts with another functional

group. In fact, "derivatized" is mentioned in numerous instances in U.S. Patent Publication No. 2002/0098222, which has been made of record in this case. (See Amendment After Final at page 7, and the final Office Action dated November 24, 2003). Applicants' use of "derivatization" is consistent with accepted usage of this term. For example, as noted in the specification with respect to an example of the present invention, derivatization with COO^- , refers to a reaction, in which "amine groups on the native collagen molecule were derivatized with COO^- groups" (specification at page 10, lines 9-10). In a further example, *glutaric anhydride* is reacted with collagen in order to obtain such derivatization with a COO^- functional group (specification at page 9, lines 6-8).

In the Office Action, the Examiner contends that teachings in Browdie of collagen reactions with glutamate and glutaraldehyde are "the same process as the Applicant's", and thus the Examiner apparently asserts that such teachings constitute collagen derivatization with a COO^- functional group. The reactions disclosed in Browdie are not the same as that disclosed in Applicants' specification, such as, at pages 9 and 10. In particular, Applicants disclose, for example, reaction of *glutaric anhydride*, while Browdie, as acknowledged by the Examiner, describes reaction with glutaraldehyde and glutamate (see Office Action at page 3). Glutaric anhydride is *not* the same as glutaraldehyde and glutamate, and the effects of these chemicals on collagen is different as well. In particular, reaction with glutaric anhydride, as disclosed in Applicants' specification and noted above, yields collagen derivatized with a COO^- functional group, while reaction with glutamate and glutaraldehyde yields *cross-linked*

collagen. The Examiner acknowledges as much in the Office Action: "Browdie refers to the alcohols he is using as 'cross-linking agents.'" Office Action at page 3.

Crosslinking is not derivatization. Cross-linking is "the establishing of chemical links between the molecular chains in polymers." (see attached definition of crosslinking from the CRC Press LLC, and available online at:

<http://composite.about.com/library/glossary/c/bldef-c1378.htm>) (See Exhibit A).

On the other hand, derivatization with a COO⁻ functional group, as discussed above, as recited in claim 1, and as described in Applicants' specification refers to a reaction with functional groups, such as amine groups (NH₃⁺), on the collagen molecule with a COO⁻ functional group. Cross-linking does not occur. Rather, as noted above, the claimed collagen is gelatinized instead. Accordingly, disclosure in Browdie of crosslinking teaches away from Applicants' claimed gelatinized collagen derivatized with a COO⁻ functional group, as recited in claim 1. Moreover, Browdie fails to teach or suggest the claimed collagen a concentration at least equal to 300 mg/ml, but less than 800 mg/ml, as further recited in claim 1.

The Examiner relies on Bass et al. allegedly for teaching "a laser with an adhesive both reduces trauma to the wound and increases weld strength." Office Action at page 4. Even if such teachings were present in Bass et al. and combinable with Browdie in the manner proposed by the Examiner, Bass et al. would still fail to overcome the above-described shortcomings of Browdie et al.

Claim 1, therefore, is allowable over Browdie and Bass et al., and claims 2, 3, 5, 6, and 8 are allowable at least due to their dependence from claim 1.

Applicants respectfully traverse the Examiner's rejection of claims 4 and 7 under 35 U.S.C. § 103 as being unpatentable over Browdie in view of Bass et al. and further in view of Poppas. The Examiner asserts that Poppas discloses "using a temperature sensing means along with a laser." Office Action at page 4. Poppas, however, like Browdie and Bass et al., also fails to teach the claimed method including providing an adhesive "including collagen, said adhesive including collagen, a concentration of said collagen in said adhesive being at least equal to 300 mg/ml, but less than 800 mg/ml, said collagen being gelatinized by application of thermal energy, and said collagen being derivatized with a COO⁻ functional group," as recited in claim 1. Accordingly, Poppas fails to overcome the deficiencies of Browdie and Bass et al. described above, and claims 4 and 7 are thus allowable at least due to their dependence from claim 1.

Applicants note that new claim 9 depends from claim 1 and recites "wherein said electromagnetic radiation has a wavelength in a range of 1.4 μm – 1.5 μm ." Support for new claim 9 may be found in the specification, for example, at page 15, lines 3-9. Applicants respectfully submit that the applied references fail to teach or suggest the method of new claim 9. New claim 9, therefore, is allowable at least due to its dependence from claim 1.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

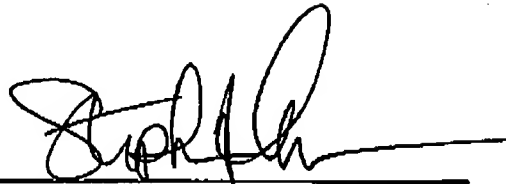
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 02-0900.

Respectfully submitted,

Dated:

11/16/04

By:



Stephen Holmes
Reg. No. 34,621

Barlow, Josephs & Holmes, Ltd.
101 Dyer Street
5th Floor
Providence, RI 02903
401 273 4446 (tel)
401 273 4447 (fax)
sjh@barjos.com

Attachments: Exhibit A